INTERNATIONAL STANDARD

ISO 17510

First edition
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Medical devices — Sleep apnoea breathing therapy — Masks and application accessories

Dispositifs médicaux — Thérapie respiratoire de l'apnée du sommeil — Masques et accessoires d'application

Reference number
ISO 17510:2015(E)

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment*.

This first edition cancels and replaces the second edition of ISO 17510-2:2007 which has been technically revised with the following changes:

— removing the SINGLE FAULT CONDITION testing for REBREATHING for nasal-only MASKS as PATIENTS can breathe through their mouth in that circumstance;

— referencing ISO 80601-2-70 for SLEEP APNOEA THERAPY EQUIPMENT.

NOTE ISO 17510-1 was replaced by ISO 80601-2-70.

Introduction

Sleep apnoea is the clinically significant intermittent absences of normal respiration occurring during sleep. The awareness of the RISKS associated with sleep apnoea has grown significantly in recent years. As a result, the use of SLEEP APNOEA BREATHING THERAPY EQUIPMENT has become common. This International Standard covers basic safety and essential performance requirements for MASKS and other application ACCESSORIES needed to protect PATIENTS during use of this equipment.

In this International Standard, the following print types are used:

— requirements and definitions: roman type;

— *test specifications: italic type*;

— informative material appearing outside of tables, such as notes, examples, and references: in smaller type. Normative text of tables is also in a smaller type;

— TERMS DEFINED IN CLAUSE 3 IN THIS INTERNATIONAL STANDARD OR AS NOTED: SMALL CAPITALS TYPE.

In referring to the structure of this International Standard, the term

— “clause” means one of the numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 5 includes 5.1, 5.2, etc.), and

— “subclause” means a numbered subdivision of a clause (e.g. 5.1, 5.2, and 5.3.1 are all subclauses of Clause 5).

References to clauses within this International Standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this particular International Standard are by number only.

In this International Standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this International Standard conform to usage described in ISO/IEC Directives Part 2, Annex H. For the purposes of this International Standard, the auxiliary verb:

— “shall” means that compliance with a requirement or a test is mandatory for compliance with this International Standard;

— “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this International Standard;

— “may” is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex A.

The attention of Member Bodies is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised ISO publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication not be adopted for mandatory implementation nationally earlier than three years from the date of publication for equipment newly designed and not earlier than five years from the date of publication for equipment already in production.

Medical devices — Sleep apnoea breathing therapy — Masks and application accessories

1 Scope

This International Standard applies to MASKS and their ACCESSORIES used to connect SLEEP APNOEA BREATHING THERAPY EQUIPMENT to the PATIENT. It specifies requirements for MASKS and ACCESSORIES, including any connecting element, that are required to connect the PATIENT-CONNECTION PORT of SLEEP APNOEA BREATHING THERAPY EQUIPMENT to a PATIENT for the application of sleep apnoea breathing therapy (e.g. nasal MASKS, EXHAUST PORTS and HEADGEAR).

SLEEP APNOEA BREATHING THERAPY EQUIPMENT is covered by ISO 80601-2-70. Figure A.1 shows the typical elements of this International Standard together with the SLEEP APNOEA BREATHING THERAPY EQUIPMENT of ISO 80601-2-70 that form a sleep apnoea breathing system.

This International Standard does not cover ORAL APPLIANCES.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 3744:2010, *Acoustics — Determination of sound power levels and sound energy levels of noise sources using sound pressure — Engineering methods for an essentially free field over a reflecting plane*

ISO 4135:2001, *Anaesthetic and respiratory equipment — Vocabulary*

ISO 4871:1996, *Acoustics — Declaration and verification of noise emission values of machinery and equipment*

ISO 5356-1:2015, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets*

ISO 5356-2:2012, *Anaesthetic and respiratory equipment — Conical connectors — Part 2: Screw-threaded weight-bearing connectors*

ISO 10993-1:2009, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 14937:2009, *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices*

ISO 15223-1:2012, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 17664:2004, *Sterilization of medical devices — Information to be provided by the manufacturer for the processing of resterilizable medical devices*

ISO 23328-1:2003, *Breathing system filters for anaesthetic and respiratory use — Part 1: Salt test method to assess filtration performance*

ISO 23328-2:2002, *Breathing system filters for anaesthetic and respiratory use — Part 2: Non-filtration aspects*

ISO 80601-2-70:2015, *Medical Electrical Equipment — Part 2-70: Particular requirements for basic safety and essential performance of sleep apnoea breathing therapy equipment*

IEC 60601-1:2005+A1:2012, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 61672-1:2013, *Electroacoustics — Sound level meters — Part 1: Specifications*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 4135:2001, ISO 17664:2004, ISO 23328-2:2002, ISO 80601-2-70:2015, IEC 60601-1:2005+A1:2012 and the following apply.

NOTE An alphabetical index of defined terms is found in Annex J.

3.1
ANTI-ASPHYXIA VALVE
valve used on a MASK, which covers the mouth and is opened to atmosphere when the SLEEP APNOEA BREATHING THERAPY EQUIPMENT is not providing adequate pressure at the MASK, and that is closed to atmosphere when the SLEEP APNOEA BREATHING THERAPY EQUIPMENT is providing adequate pressure at the MASK

3.2
EXHAUST FLOW
flow from the MASK or application ACCESSORY to atmosphere other than the leak due to improper seal to the face

Note 1 to entry: The EXHAUST FLOW can pass through openings in the MASK, the connecting element and the MASK, or through the ANTI-ASPHYXIA VALVE.

Note 2 to entry: The EXHAUST FLOW discharges exhaled gases to atmosphere to reduce REBREATHING of CO_2.

3.3
EXPECTED USEFUL LIFE
time period specified by the MANUFACTURER during which the MEDICAL DEVICE or ACCESSORY is expected to remain suitable for use under the conditions specified by the MANUFACTURER

Note 1 to entry: CLEANING and other PROCESSING can be necessary during the EXPECTED USEFUL LIFE.

3.4
HEADGEAR
part that is used to fix the MASK to the PATIENT

3.5
MASK
part which provides the interface between the PATIENT and the PATIENT-CONNECTION PORT

Note 1 to entry: According to their application, MASKS are divided into nasal MASKS, oral MASKS, or nasal-oral MASKS.

3.6
MULTI-PATIENT REUSE
capable of being re-used multiple times on multiple PATIENTS

3.7
ORAL APPLIANCE
device intended to maintain the oral airway by mechanical means and which achieves its purpose independently of SLEEP APNOEA BREATHING THERAPY EQUIPMENT

3.8
SINGLE FAULT CONDITION
condition of ME EQUIPMENT or ACCESSORY in which a single means for reducing a RISK is defective or a single abnormal condition is present

[SOURCE: IEC 60601-1:2005+A1:2012, 3.116, modified—added 'or ACCESSORY' and deleted note.]

3.9
SINGLE-PATIENT REUSE
capable of being used multiple times on the same PATIENT

4 Information to be supplied by the MANUFACTURER

4.1 General

MASKS, HEADGEAR and other ACCESSORIES shall be provided with an ACCOMPANYING DOCUMENT. The ACCOMPANYING DOCUMENT shall be regarded as a part of MASKS, HEADGEAR and the ACCESSORIES.

NOTE 1 The purpose of an ACCOMPANYING DOCUMENT is to promote the safe use of a MASK, HEADGEAR or other ACCESSORY during the EXPECTED USEFUL LIFE.

NOTE 2 Annex H contains a guide to assist the reader in locating the marking and labelling requirements contained in other clauses of ISO 17510.

4.2 Marking on the protective packaging

Packages of MASKS, HEADGEAR and other ACCESSORIES shall be marked with:

a) name or trade name and address of

- the MANUFACTURER, and
- where the MANUFACTURER does not have an address within the locale, an authorized representative within the locale,

to which the OPERATOR or RESPONSIBLE ORGANIZATION can refer;

b) the details strictly necessary to identify the device and the contents of the packaging especially for the OPERATOR or RESPONSIBLE ORGANIZATION;

c) the identity and intended purpose of the MASK and any application ACCESSORIES;

d) any special storage and/or handling conditions;

e) any special operating instructions;

f) any special warnings and/or precautions to be taken;

g) if applicable, symbol from ISO 15223-1:2012, 5.1.4 indicating the latest date by which the MASK and any application ACCESSORIES can be used safely (i.e. shelf life), expressed as the year, month and day;

h) identification reference to the batch, type or serial number with symbol from ISO 15223-1:2012, 5.1.7 with an accompanying serialization or symbol from ISO 15223-1:2012, 5.1.5 with an accompanying lot or batch identifier; and

i) for sterile items, with symbol ISO 15223-1:2012, 5.2.1, symbol ISO 15223-1:2012, 5.2.2, symbol ISO 15223-1:2012, 5.2.3 or symbol ISO 15223-1:2012, 5.2.4, as appropriate.

Packaging for single use MASKS, HEADGEAR and other ACCESSORIES shall be marked accordingly and shall be consistent for a MODEL OR TYPE REFERENCE.

Check compliance by inspection without opening the packaging.

4.3 Accompanying document

The ACCOMPANYING DOCUMENT of the MASK, HEADGEAR, or other ACCESSORY shall contain the following information:

a) name or trade name and address of

— the MANUFACTURER; and

— where the MANUFACTURER does not have an address within the locale, an authorized representative within the locale,

to which the OPERATOR or RESPONSIBLE ORGANIZATION can refer;

b) the identity and the intended purpose of the MASK and any application ACCESSORIES;

c) the details of any treatment or handling needed before the MASK or ACCESSORY can be used;

d) if provided sterile,

— an indication of the method of sterilization using symbol ISO 15223-1:2012, 5.2.1, symbol ISO 15223-1:2012, 5.2.2, symbol ISO 15223-1:2012, 5.2.3 or symbol ISO 15223-1:2012, 5.2.4, as appropriate;

— instructions necessary in the event of damage to the sterile packaging and details of appropriate methods of resterilization;

e) if the packaging contains more than one component information necessary for correct assembly of the components;

f) information necessary to verify whether the MASK or ACCESSORY is properly installed and can operate correctly and safely;

g) if the MASK or ACCESSORY includes an EXHAUST PORT, a warning statement to the effect that: “WARNING: Occlusion of the exhaust needs to be prevented to avoid having an adverse effect on the safety and quality of the therapy”;

h) a statement to the effect that combination with other medical devices not intended to be combined with the mask can decrease the safety or alter the performance of the mask (e.g. in combination with a humidifier for medical use, nebulizer, heat and moisture exchanger (HME), filters, bi-level positive airway pressure equipment, self-adjusting equipment, or additional oxygen supply or any exhaust port);

i) if applicable, information about the means provided to minimize REBREATHING (see 5.3);

j) the RATED pressure range of the MASK including any connecting element;

k) information to enable the RESPONSIBLE ORGANIZATION (prescriber) to inform the PATIENT of

— any potential contraindications and any precautions that might need to be taken,

— any precautions to be taken in the event of changes in performance, and

— any precautions to be taken regarding to risks associated with disposal;

l) if specified for reuse:

— the information specified in ISO 17664:2004, 3.9, if sterilizable;

— a warning statement to the effect that: “WARNING: frequency of cleaning, methods of cleaning or the use of cleaning agents, other than those specified in the accompanying documents, or

exceeding the number of PROCESSING cycles can have an adverse effect on the [place name of component here] and consequently the safety or the quality of the therapy";

m) information about the nature and frequency of regular and preventative maintenance of the MASK or ACCESSORY, including information about the replacement of consumable components during the EXPECTED USEFUL LIFE of the MASK or ACCESSORY;

n) information for the OPERATOR to identify parameters or criteria that could indicate a safety or efficacy change in the MASK or ACCESSORY (e.g. visual inspection criteria); as well as the course of action to follow as a result of this identification (e.g. disposal or component replacement procedure);

o) the EXPECTED USEFUL LIFE of MASKS and any ACCESSORIES;

p) * the resistance, derived from pressure drop, between the MASK and the PATIENT-CONNECTION PORT at flowrates of 50 l/min and 100 l/min, as determined in Annex C;

q) * for MASKS that cover the nose and the mouth, the inspiratory, and expiratory resistance of the MASK in combination with the ANTI-ASPHYXIA VALVE open to atmosphere, as determined in Annex E;

r) * the pressure-flow curve of the EXHAUST FLOW throughout the working pressure range as determined in Annex B;

s) * the date of issue or revision level of the ACCOMPANYING DOCUMENT.

Check compliance by inspection of the ACCOMPANYING DOCUMENT.

5 Construction requirements

5.1 MASK connectors

MASK connectors, if conical, shall be 15 mm or 22 mm size male connectors conforming to ISO 5356-1:2015 or ISO 5356-2:2012.

Non-conical MASK connectors shall not engage with conical connectors conforming to ISO 5356-1:2015 or ISO 5356-2:2012, unless they comply with the engagement, disengagement, and leakage requirements of ISO 5356-1:2015 or ISO 5356-2:2012.

Check compliance by inspection and functional testing.

5.2 Biocompatibility

Parts or materials that are intended to be in contact with the PATIENT or PATIENT gas pathway during NORMAL USE shall be evaluated according to ISO 10993-1:2009.

NOTE 1 The gas pathways should be evaluated to ISO 18562-1:—, upon its publication.

Parts or materials that are intended to be inserted into the nares or the mouth shall be evaluated as mucosal membrane contact.

For parts or materials not intended to be inserted into the nares or mouth (e.g. MASK elbows, tubing, cushions, and faceplates), the gas pathway materials shall be evaluated as skin contact.

For MASK materials, including HEADGEAR, intended to contact the PATIENT'S head, the materials shall be evaluated as skin contact.

All materials shall be considered as for permanent duration contact as categorized in ISO 10993-1:2009.

NOTE 2 Permanent duration contact is required because SLEEP APNOEA BREATHING THERAPY EQUIPMENT and ACCESSORIES have cumulative usage that is greater than 30 d.

Natural rubber latex shall not be used in the MASK or ACCESSORIES.

The MANUFACTURER of a MASK or ACCESSORIES shall address in the RISK MANAGEMENT PROCESS the RISKS associated with the leaching or leaking of substances into the gas pathway. Special attention shall be given to substances which are carcinogenic, mutagenic, or toxic to reproduction.

A MASK or ACCESSORY that contains phthalates which are classified as carcinogenic, mutagenic or toxic to reproduction shall be marked on the MASK or ACCESSORY itself or on the packaging that it contains phthalates. If the INTENDED USE of a MASK or ACCESSORY includes treatment of children or treatment of pregnant or nursing women, a specific justification for the use of these phthalates shall be included in the RISK MANAGEMENT FILE. The ACCOMPANYING DOCUMENT of a MASK or ACCESSORY that contains such phthalates shall contain information on RESIDUAL RISKS for these PATIENT groups and, if applicable, on appropriate precautionary measures.

Check compliance by the application of ISO 10993-1:2009, inspection of the ACCOMPANYING DOCUMENT and inspection of the RISK MANAGEMENT FILE for identification of the presence of substances which are carcinogenic, mutagenic or toxic to reproduction and justification for their use.

5.3 * Protection against REBREATHING

5.3.1 NORMAL CONDITION protection

Means shall be provided to minimize the RISK of REBREATHING during NORMAL CONDITION. The means may be integral to the MASK or other application ACCESSORY or located in the SLEEP APNOEA BREATHING THERAPY EQUIPMENT.

Under NORMAL CONDITION, the relative CO_2 increase shall not exceed 20 % when tested at

— the minimum RATED pressure,

— a pressure of 5 hPa (5 cmH_2O), and

— a pressure of 10 hPa (10 cmH_2O).

Check compliance by the tests described in Annex F.

5.3.2 SINGLE FAULT CONDITION PROTECTION

MASKS that cover the mouth shall be designed to minimize REBREATHING during SINGLE FAULT CONDITION.

Under SINGLE FAULT CONDITION, the relative CO_2 increase shall not exceed 60 % when tested

— with blockage of the BREATHING TUBE, and

— at the equipment-end of the BREATHING TUBE open to atmosphere.

NOTE PATIENTS can open their mouth and breathe normally under SINGLE FAULT CONDITION for a MASK that only covers the nose.

Check compliance by the tests described in Annex F.

5.4 CLEANING, DISINFECTION, and sterilization

The MASK and any ACCESSORIES, whether for SINGLE-PATIENT REUSE or MULTI-PATIENT REUSE, shall be designed so that contaminant-trapping features are minimized and can be easily cleaned by the OPERATOR.

The MASK and any ACCESSORIES and their parts intended for MULTI-PATIENT REUSE shall be so constructed that they can be cleaned and disinfected or cleaned and sterilized.

PROCESSING or (re)PROCESSING methods for CLEANING and DISINFECTION of a MASK and any ACCESSORIES and their parts shall be validated using the number of CLEANING or CLEANING and DISINFECTION cycles that represents their EXPECTED USEFUL LIFE.

PROCESSING or (re)PROCESSING instructions disclosed in the ACCOMPANYING DOCUMENT for the MASK and any ACCESSORIES and their parts shall comply with ISO 17664:2004 and ISO 14937:2009. The MASK and any ACCESSORIES labelled sterile shall have been sterilized using an appropriate, validated method as described in ISO 14937:2009.

Non-sterile packaging systems shall be designed to maintain contents, which are intended to be sterilized before use, at their intended level of cleanliness.

Check compliance by inspection of ACCOMPANYING DOCUMENT and review of the validation of the PROCESSING methods, including the verification that the MASK and any ACCESSORIES and their parts comply with their specifications after re-PROCESSING.

5.5 * Breathing during SINGLE FAULT CONDITION

For MASKS that cover the mouth, means shall be provided to limit inspiratory and expiratory resistance in SINGLE FAULT CONDITION. The resistance to flow shall not exceed 10 hPa (10 cmH_2O) (measured at the PATIENT-CONNECTION PORT) at a flowrate of 50 l/min.

If an ANTI-ASPHYXIA VALVE is provided, the open-to-atmosphere pressure shall be less than the minimum RATED pressure of the MASK. The open-to-atmosphere and closed-to-atmosphere pressures shall be disclosed in the ACCOMPANYING DOCUMENT.

NOTE PATIENTS can open their mouth and breathe normally under SINGLE FAULT CONDITION for a MASK that only covers the nose.

Check compliance by inspection of ACCOMPANYING DOCUMENT and using the tests described in Annex D and Annex E.

5.6 Breathing system filter

Any BREATHING SYSTEM FILTER shall comply with ISO 23328-1:2003 and ISO 23328-2:2002.

Check compliance by application of the requirements of ISO 23328-1:2003 and ISO 23328-2:2002.

6 Vibration and noise

The A-weighted sound power level caused by the MASK and any ACCESSORIES shall be measured and disclosed in the ACCOMPANYING DOCUMENT in accordance with ISO 4871:1996 and ISO 3744:2010 using engineering-method grade 2. The A-weighted sound pressure level in accordance with ISO 4871:1996 and ISO 3744:2010 at a distance of 1 m shall also be disclosed in the ACCOMPANYING DOCUMENT.

NOTE Care is required in the test setup to ensure that the sound measurement of the MASK and any ACCESSORIES is not interfered with by the noise emitted by the BREATHING TUBE or the equipment.

Check compliance by inspection of ACCOMPANYING DOCUMENT and the tests in Annex G.

Annex A
(informative)

Particular guidance and rationale

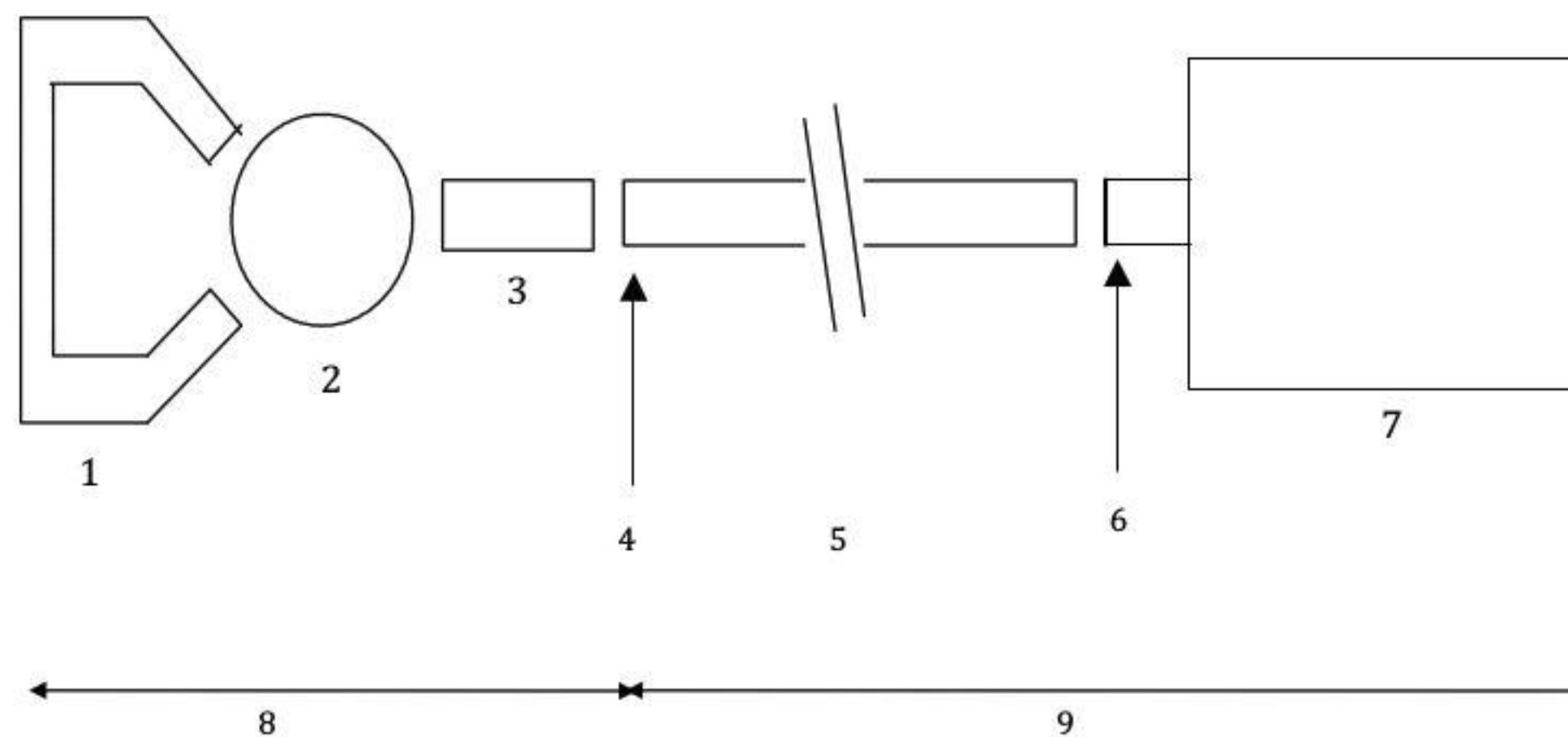
A.1 General guidance

This Annex provides rationale for some requirements of this International Standard and is intended for those who are familiar with the subject of this International Standard but who have not participated in its development. An understanding of the rationales underlying these requirements is considered to be essential for their proper application. Furthermore, as clinical practice and technology change, it is believed that a rationale will facilitate any revision of this document necessitated by those developments.

Figure A.1 is a typical example of a series of component arrangements of ISO 80601-2-70 and ISO 17510. It is intended to enhance comprehension of the combination of SLEEP APNOEA BREATHING THERAPY EQUIPMENT and MASKS and application ACCESSORIES, as well as to clarify the scope of the related standards.

SLEEP APNOEA BREATHING THERAPY EQUIPMENT is usually combined with a MASK and application ACCESSORIES of different MANUFACTURERS. Whereas most SLEEP APNOEA BREATHING THERAPY EQUIPMENT is pressure-adjustable at the PATIENT-CONNECTION PORT, all connected ACCESSORIES and MASKS are outside the area where pressure is controlled. Therefore, these MASKS have direct impact on the therapeutic pressure received by the PATIENT. An important mechanism whereby SLEEP APNOEA BREATHING THERAPY EQUIPMENT benefits the PATIENT is by increasing the cross-sectional area of the pharynx and decreasing the collapsibility of the upper airway. SLEEP APNOEA BREATHING THERAPY EQUIPMENT is intended to deliver a therapeutic pressure to the PATIENT by means of MASKS and/or application ACCESSORIES.

The resistance of MASKS and ACCESSORIES connected to SLEEP APNOEA BREATHING THERAPY EQUIPMENT depends on respiratory flowrate. High inspiratory peak flows, in particular, can cause a substantial pressure drop between the PATIENT-CONNECTION PORT and the PATIENT'S airway. Consequently, the PATIENT does not receive the required therapeutic pressure, the probability of obstructive apnoea is increased, and the therapeutic objective is not achieved. Furthermore, SLEEP APNOEA BREATHING THERAPY EQUIPMENT relies on both the design of the SLEEP APNOEA BREATHING THERAPY EQUIPMENT to minimize the RISK of asphyxia and the defence mechanism of the PATIENT to respond to SINGLE FAULT CONDITIONS and arouse the PATIENT from sleep, thereby allowing the PATIENT to avoid potential HARM. Therefore, this International Standard deals extensively with the performance standard for SLEEP APNOEA BREATHING THERAPY EQUIPMENT to ensure the delivery of the therapeutic pressure and prevent asphyxia.

The requirements and test methods stated serve to provide guidance to RESPONSIBLE ORGANIZATIONS and OPERATORS when selecting appropriate SLEEP APNOEA BREATHING THERAPY EQUIPMENT, MASKS, ACCESSORIES and the combination thereof, and to ensure compatibility of the MASKS and ACCESSORIES with SLEEP APNOEA BREATHING THERAPY EQUIPMENT.

Key

1 HEADGEAR

2 MASK

3 connecting element (optional)

4 PATIENT-CONNECTION PORT

5 BREATHING TUBE

6 GAS OUTPUT PORT connector of the SLEEP APNOEA BREATHING THERAPY EQUIPMENT

7 SLEEP APNOEA BREATHING THERAPY EQUIPMENT with or without humidifier

8 scope of ISO 17510

9 scope of ISO 80601-2-70

NOTE The EXHAUST PORT can be located in the connecting element (3), the MASK (2), or the SLEEP APNOEA BREATHING THERAPY EQUIPMENT (6).

Figure A.1 — Relationship of the components of SLEEP APNOEA BREATHING THERAPY EQUIPMENT and MASKS and application ACCESSORIES and the related standards

A.2 Rationale for particular clauses and subclauses

The numbering of the following rationales corresponds to the numbering of the clauses in this International Standard. The numbering is, therefore, not consecutive.

Subclause 4.3 — ACCOMPANYING DOCUMENT

p)

The EXHAUST FLOW comprises flow through all orifices in the MASK and ACCESSORIES (including the EXHAUST PORT).

EXHAUST FLOW and the derived pressure-flow curve are important characteristics of the MASK which assist the supervising clinician or the healthcare professional OPERATOR in assessing the compatibility of the MASK with other equipment. The relationship between the pressure provided to the PATIENT and the EXHAUST FLOW is measured and included in the labelling.

The settings chosen for the test were selected to be consistent with ISO 80601-2-70:2015, Table 201.104.

q)

The total resistance to flow in SLEEP APNOEA BREATHING THERAPY EQUIPMENT and MASKS and application ACCESSORIES comprises the resistance up to the PATIENT-CONNECTION PORT, plus the resistance of the MASK and application ACCESSORIES from the PATIENT-CONNECTION PORT to the PATIENT.

The resistance up to the PATIENT-CONNECTION PORT is addressed in equipment design in ISO 80601-2-70:2015. The resistance of the MASK and application ACCESSORIES from the PATIENT-CONNECTION PORT to the PATIENT is an important characteristic that assists the RESPONSIBLE ORGANIZATION in assessing the compatibility of the MASK and application ACCESSORIES with other equipment.

The resistance of the MASK and application ACCESSORIES changes with the flow, and this relationship depends on the design. Therefore, a single measurement point is not adequate. The resistance is measured at two typical flows at the PATIENT-CONNECTION PORT (50 l/min and 100 l/min).

The pressure drop is provided, rather than the calculated resistance. Pressure drop is more useful to the supervising clinician or the healthcare professional OPERATOR.

Specifying the resistance to flow of the MASK and application ACCESSORIES allows the supervising clinician or the healthcare professional OPERATOR to specify compatible SLEEP APNOEA BREATHING THERAPY EQUIPMENT.

r)

Specifying the inspiratory resistance of the ANTI-ASPHYXIA VALVE of the MASK at a very low flowrate allows the supervising clinician or the healthcare professional OPERATOR to specify compatible SLEEP APNOEA BREATHING THERAPY EQUIPMENT so that the ANTI-ASPHYXIA VALVE closes when needed. Annex E contains additional information.

Specifying the expiratory resistance of the ANTI-ASPHYXIA VALVE of the MASK allows the supervising clinician or the healthcare professional OPERATOR to specify compatible SLEEP APNOEA BREATHING THERAPY EQUIPMENT so that the ANTI-ASPHYXIA VALVE closes when needed. Annex E contains additional information.

Subclause 5.3 — Protection against REBREATHING

MASKS and other PATIENT interfaces intended for use with SLEEP APNOEA BREATHING THERAPY EQUIPMENT without an active exhalation valve incorporate an EXHAUST PORT. The function of the EXHAUST PORTS is to allow for passive removal of exhaled gases to minimize REBREATHING.

A critical issue to be considered is whether the machine-PATIENT flow through the EXHAUST PORT has reduced the residual exhaled CO_2 to acceptable levels.

Most SLEEP APNOEA BREATHING THERAPY EQUIPMENT is equipped with a single-conduit BREATHING GAS PATHWAY with a dual-purpose, inspiratory/expiratory function and an EXHAUST PORT. The issue of CO_2 REBREATHING will be a function of several variables, such as the following:

— the type of the breathing attachment — face MASK, nasal MASK, or full face MASK;

— the size and location of the EXHAUST PORTS;

— the average flowrate at the minimum CPAP pressure;

NOTE The average flowrate is measured in ISO 80601-2-70:2015, Annex C and recorded in Table C.1, which allows the supervising clinician or the healthcare professional OPERATOR to assess the potential for REBREATHING.

— the duration of the PATIENT'S exhalation.

There is the potential for clinically significant CO_2 REBREATHING if the EXHAUST PORTS are not designed and located appropriately. Therefore, the design and configuration of SLEEP APNOEA BREATHING THERAPY EQUIPMENT and its MASKS and ACCESSORIES has a major impact on the potential for REBREATHING of carbon dioxide and thereby the inspired oxygen concentration.

The maximum recommended time-weighted average for inspired CO_2 in industry is 1 %. An inspired CO_2 fraction of 1 % would add 1 013,25 Pa (7,6 torr) to the test model in Annex F and would result in the test end-tidal CO_2 value of 1 013,25 Pa (7,6 torr) + 5 066,25 Pa (38 torr) or 6 079,5 Pa (45,6 torr). This represents a 20 % increase in the CO_2 level. Based on this, the committee chose a 20 % increase in the

CO_2 level NORMAL CONDITION limit. Similarly, the 60 % increase in the CO_2 level SINGLE FAULT CONDITION limit represents a time-weighted average for an inspired CO_2 of 3 %.

Subclause 5.5 — Breathing during SINGLE FAULT CONDITION

For PATIENT safety when the SLEEP APNOEA BREATHING THERAPY EQUIPMENT ceases to provide flow, the MASK, complete with specified application ACCESSORIES, is required to satisfy the following.

— To control REBREATHING at an acceptable level by allowing adequate flushing of CO_2 when only PATIENT-generated flow is passing through the MASK. See also 5.3.

— To limit the inspiratory and expiratory resistance to an acceptable level.

One method of achieving the above requirements is to provide an ANTI-ASPHYXIA VALVE, in parallel with the EXHAUST PORT. To ensure that the functioning of the ANTI-ASPHYXIA VALVE does not impair the function of the MASK during NORMAL CONDITION, it is required to satisfy the following:

— closing pressure: the ANTI-ASPHYXIA VALVE is required to close to atmosphere at an appropriate pressure, to ensure that therapy is provided to the PATIENT;

— opening pressure: the ANTI-ASPHYXIA VALVE is required to open at an appropriate pressure, to ensure that the PATIENT is provided with a safe inspiratory and expiratory resistance and a safe level of REBREATHING, when therapy is not provided; and

— protection against opening in NORMAL USE: to ensure that therapy is provided to the PATIENT, the ANTI-ASPHYXIA VALVE is intended to remain closed while the SLEEP APNOEA BREATHING THERAPY EQUIPMENT is operating.

Annex B
(normative)

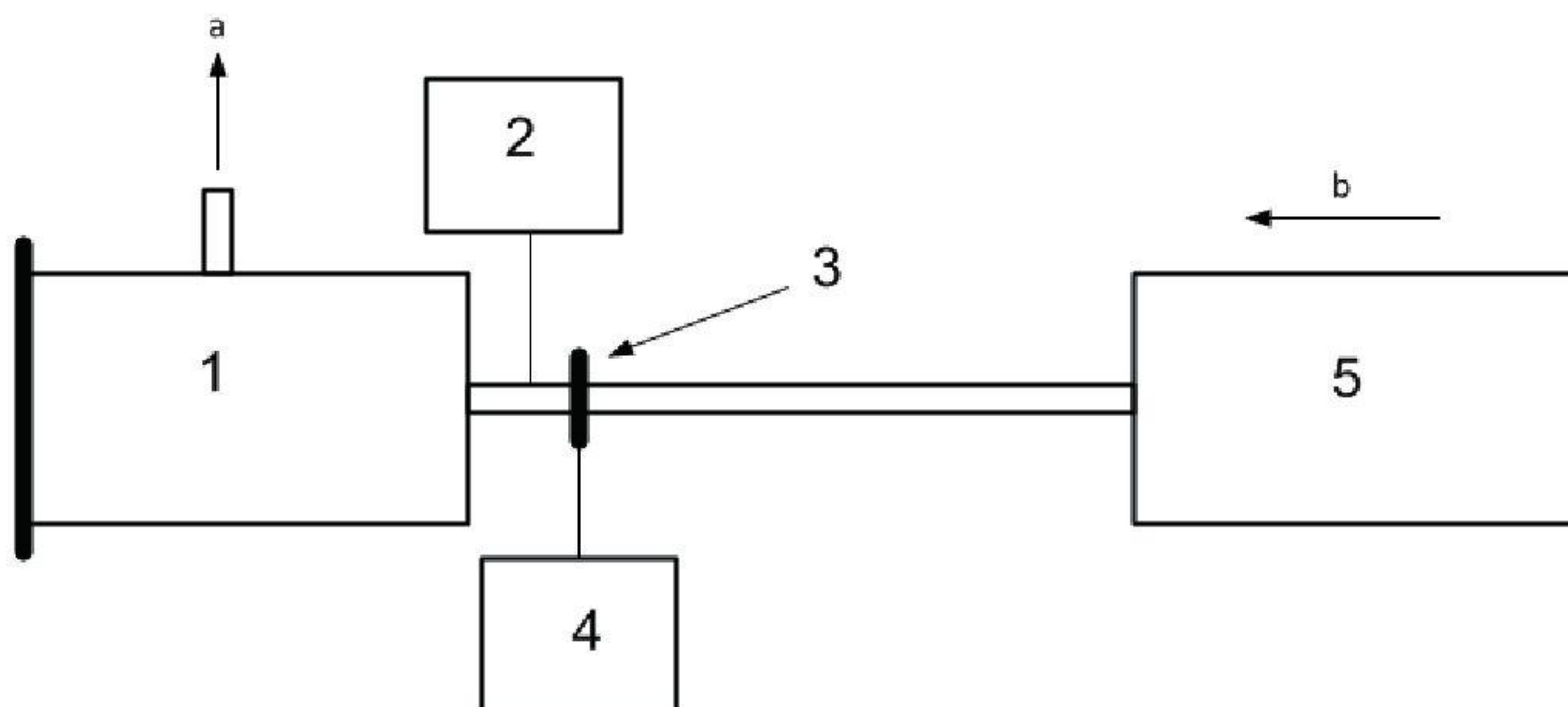
EXHAUST FLOW test procedure

B.1 Principle

The objective of this test is to determine the relationship between the pressure provided to the PATIENT and the measured EXHAUST FLOW.

B.2 Apparatus

Figure B.1 illustrates the test setup for measuring the EXHAUST FLOW.

Key

1 MASK or ACCESSORY under test

2 pressure meter

3 PATIENT-CONNECTION PORT

4 flowmeter

5 flow source

a EXHAUST FLOW.

b Flow.

Figure B.1 — Test setup for EXHAUST FLOW testing

B.3 Procedure

Carry out testing as follows.

a) *Set up the MASK or ACCESSORY and test apparatus as shown in Figure B.1.*

b) *To measure EXHAUST FLOW only, confirm that the test apparatus satisfies the following requirements:*

— *exclude the flow source (3) (flow between the flow generator and PATIENT-CONNECTION PORT) from the measurement (e.g. position the flowmeter at the PATIENT-CONNECTION PORT);*

— *position the flowmeter sensor (5) at the PATIENT-CONNECTION PORT (2);*

— *exclude the flow source (3) (at the PATIENT interface) by sealing the PATIENT interface of the MASK or other ACCESSORY and confirm that the PATIENT interface is sealed.*

c) *To measure the pressure provided to the PATIENT, confirm that the pressure sensor measures the pressure directly adjacent to the PATIENT'S nose/mouth.*

d) *Adjust the flowrate to achieve the minimum pressure in the RATED pressure range, and measure the flowrate at this point.*

e) *Repeat steps b) to d) for the following pressures (rounded to the next whole integer):*

— *minimum pressure +1/4 (maximum pressure — minimum pressure);*

— *minimum pressure +1/2 (maximum pressure — minimum pressure);*

— *minimum pressure +3/4 (maximum pressure — minimum pressure); and*

— *maximum pressure of the RATED pressure range.*

Annex C
(normative)

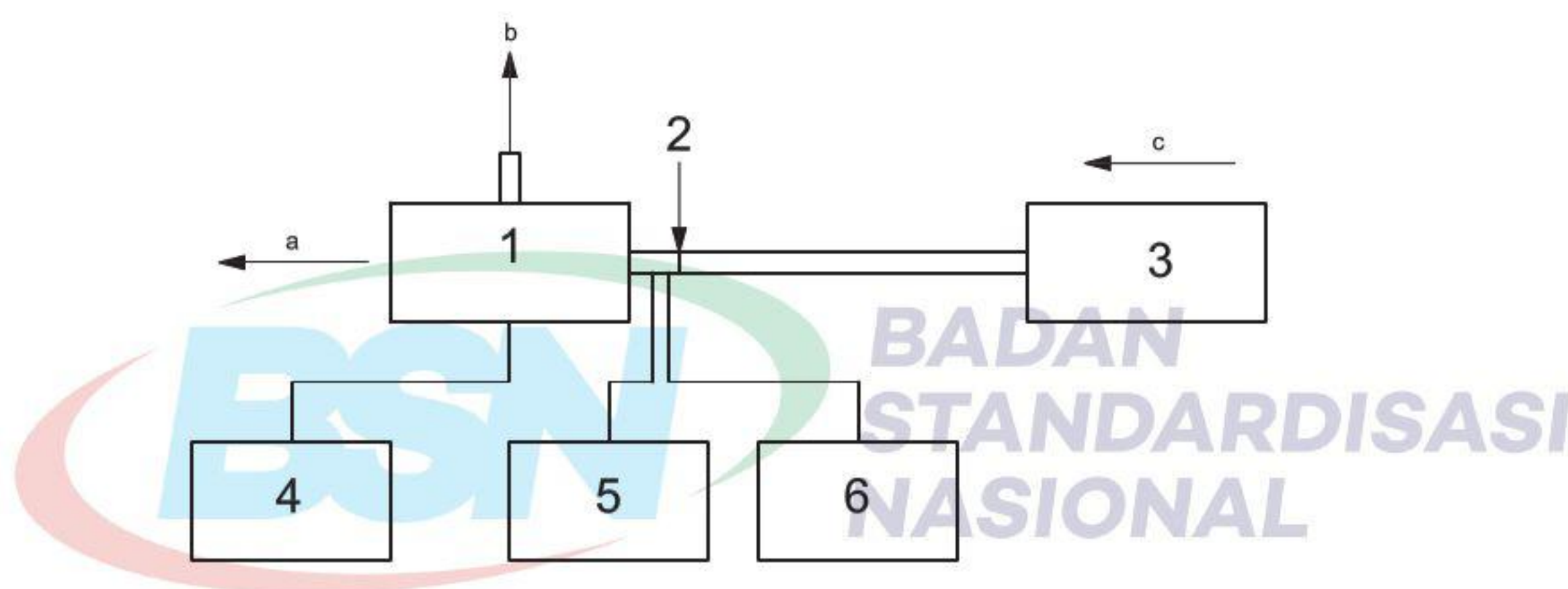
Resistance to flow (pressure drop)

C.1 Principle

The objective of this test is to measure the pressure drop from the PATIENT-CONNECTION PORT to the PATIENT at flowrates of 50 l/min and 100 l/min.

C.2 Apparatus

Figure C.1 illustrates the test setup for determining the resistance to flow.

Key

1 MASK or ACCESSORY under test
2 PATIENT-CONNECTION PORT
3 flow source
4 pressure meter 2
5 pressure meter 1
6 flowmeter
a Flow to atmosphere.
b EXHAUST FLOW.
c Flow.

NOTE Pressure meter 1 and pressure meter 2 may be a differential pressure meter.

Figure C.1 — Test setup for resistance to flow testing

C.3 Procedure

Carry out testing as follows.

a) *Set up the MASK or ACCESSORY (1) and apparatus as shown in Figure C.1. If required, leave the PATIENT interface open to the atmosphere to achieve the specified flowrates.*

b) *Measure the pressure difference between the* PATIENT-CONNECTION PORT *and a point directly adjacent to the* PATIENT*'s nose/mouth.*

c) *Adjust the flowrate to 50 l/min and measure the pressure difference in hPa (cm*H_2O*).*

d) *Repeat steps b) and c) at 100 l/min flowrate.*

Annex D
(normative)

ANTI-ASPHYXIA VALVE pressure testing

D.1 Principle

The objective of these tests is to

— determine the pressure at which the ANTI-ASPHYXIA VALVE opens to atmosphere, and

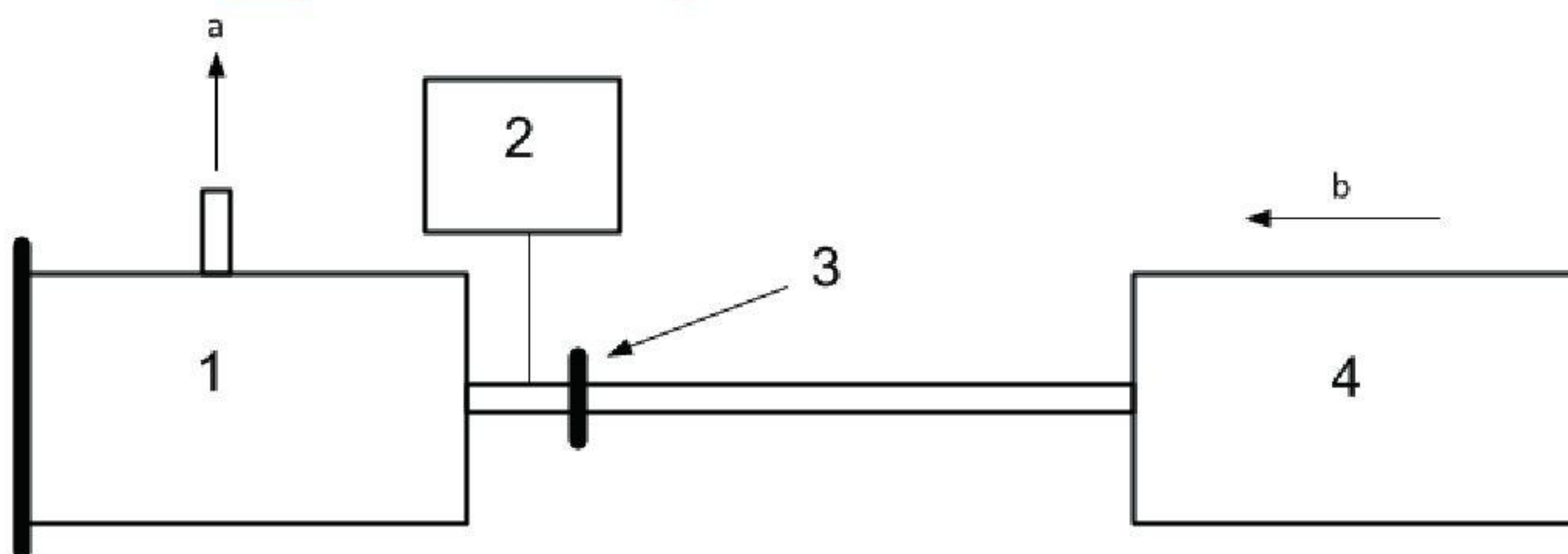
— determine the pressure at which the ANTI-ASPHYXIA VALVE closes to atmosphere.

These tests assess the means to limit breathing resistance and to prevent excessive REBREATHING when the SLEEP APNOEA BREATHING THERAPY EQUIPMENT provides insufficient flow.

The pressure at which the ANTI-ASPHYXIA VALVE opens to atmosphere shall be below the minimum RATED pressure of the SLEEP APNOEA BREATHING THERAPY EQUIPMENT.

NOTE If the pressure at which the ANTI-ASPHYXIA VALVE opens to atmosphere is not below the minimum RATED pressure of the SLEEP APNOEA BREATHING THERAPY EQUIPMENT, the ANTI-ASPHYXIA VALVE will not function.

D.2 Apparatus

Figure D.1 illustrates the test setup for ANTI-ASPHYXIA VALVE pressure testing.

Key

1 ANTI-ASPHYXIA VALVE under test

2 pressure meter

3 PATIENT-CONNECTION PORT

4 flow source

a ANTI-ASPHYXIA VALVE flow.

b Flow.

Figure D.1 — Test setup for determination of the opening and closing pressures of the ANTI-ASPHYXIA VALVE

D.3 Procedure for determining the opening pressure

Carry out opening testing as follows.

a) *Set up the apparatus to generate flow through the* BREATHING GAS PATHWAY *as indicated in* Figure D.1 *and confirm that the* ANTI-ASPHYXIA VALVE *is closed to the atmosphere.*

b) *Slowly decrease the flow from the flow source until the* ANTI-ASPHYXIA VALVE *activates and starts to open to the atmosphere.*

c) *Record the pressure at the point where the* ANTI-ASPHYXIA VALVE *starts to open to the atmosphere.*

D.4 Procedure for determining the closing pressure

Carry out closing testing as follows.

a) *Set up the apparatus to generate flow through the* BREATHING GAS PATHWAY *as indicated in* Figure D.1 *and ensure the* ANTI-ASPHYXIA VALVE *(1) is open to the atmosphere.*

b) *Slowly increase the flow from the flow source (3) until the* ANTI-ASPHYXIA VALVE *deactivates and completely closes to atmosphere.*

c) *Record the pressure at the point where the* ANTI-ASPHYXIA VALVE *closes completely.*

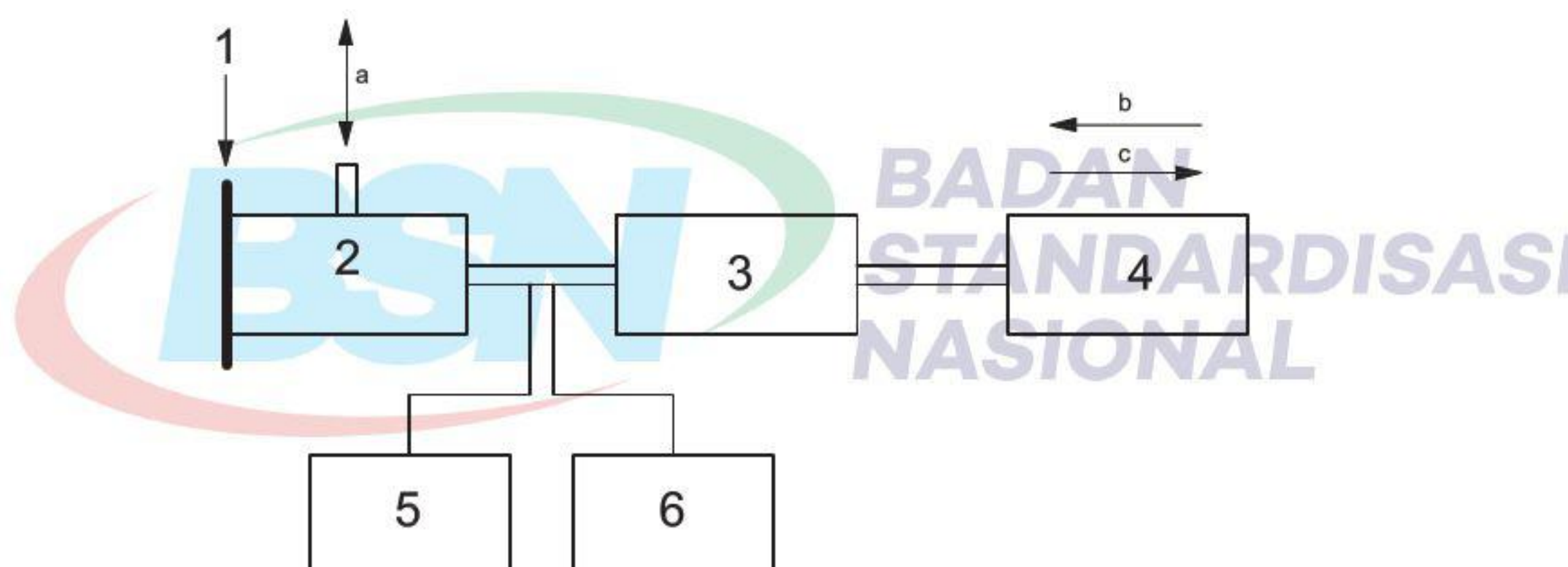
Annex E
(normative)

Determination of the inspiratory and expiratory resistance under SINGLE FAULT CONDITION

E.1 Principle

The objective of this test is to determine the inspiratory and expiratory resistance at a flowrate of 50 l/min in SINGLE FAULT CONDITION [e.g. when the ANTI-ASPHYXIA VALVE is activated (i.e. opens to the atmosphere)].

E.2 Apparatus

Figure E.1 illustrates the test setup for the determination of the inspiratory and expiratory resistance testing.

Key

1 PATIENT-CONNECTION PORT
2 ANTI-ASPHYXIA VALVE under test
3 dummy head with airway
4 flow source
5 pressure meter
6 flowmeter
a ANTI-ASPHYXIA VALVE flow.
b Expiratory flow.
c Inspiratory flow.

Figure E.1 — Test setup for determination of the inspiratory and expiratory resistance of the ANTI-ASPHYXIA VALVE

E.3 Procedure

Carry out testing as follows.

a) *Connect a variable flow source capable of generating flow to and from the flowrate measuring device.*

b) *Connect the flowrate measuring device to a dummy head with an artificial airway or other suitable fixture that will seal the* MASK.

c) *Connect the pressure meter to the* MASK.

d) *Occlude the* PATIENT-CONNECTION PORT *on the* MASK *or any other known flow path in the* MASK *that is not normally open during operation (such as pressure ports).*

e) *Leave open any normally open breathing gas paths.*

f) *Set the variable flow source to a flowrate of -50 l/min.*

g) *Read the inspiratory pressure at the pressure meter.*

h) *Set the variable flow source to a flowrate of +50 l/min.*

i) *Read the expiratory pressure at the pressure meter.*

Annex F
(normative)

Carbon Dioxide REBREATHING

F.1 Principle

The objective of the CO_2 REBREATHING test is to test the effectiveness of MASKS or other PATIENT interfaces intended for sleep apnoea breathing therapy with respect to the possibility of REBREATHING carbon dioxide (CO_2).

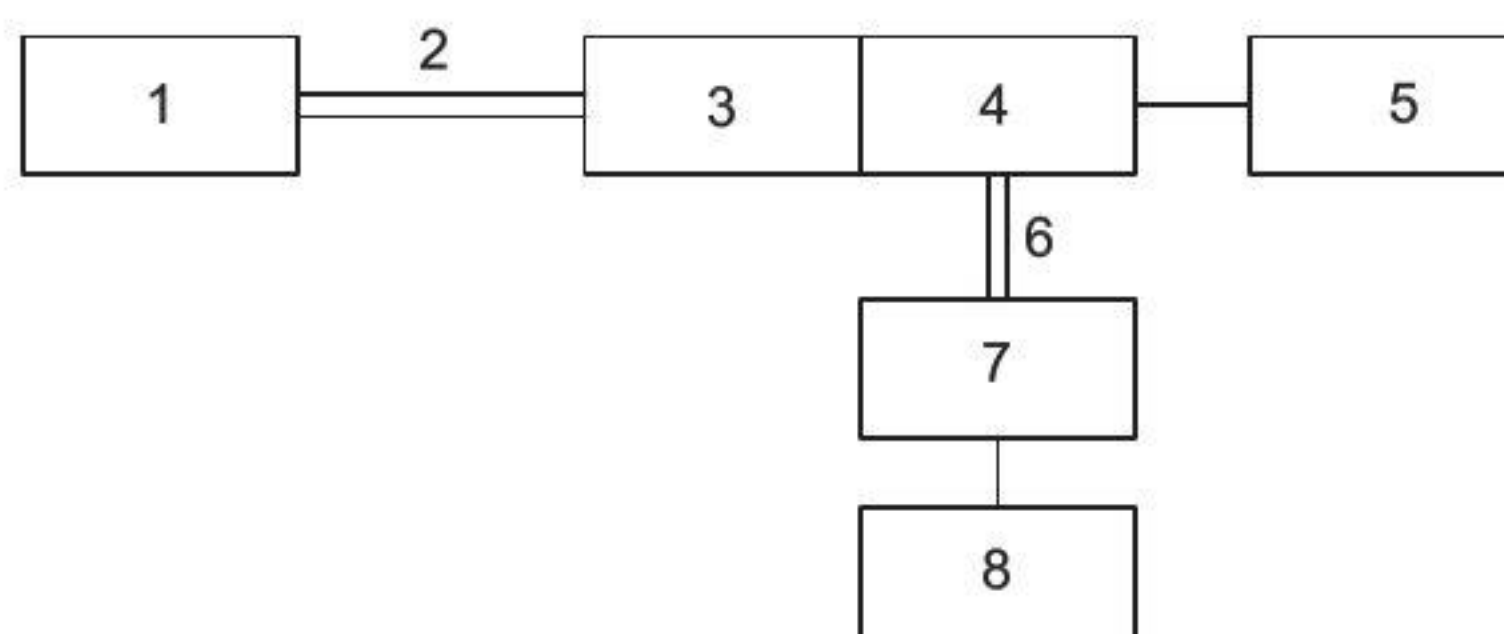
MASKS and other PATIENT interfaces intended for use with positive airway pressure equipment without an active exhalation valve incorporate an EXHAUST PORT.

NOTE For the purposes of this International Standard, an active exhalation valve is a SLEEP APNOEA BREATHING THERAPY EQUIPMENT-controlled valve through which gas is released during the exhalation phase.

The function of the EXHAUST PORT is to allow for passive removal of exhaled CO_2 to minimize REBREATHING. There is the potential for clinically significant CO_2 REBREATHING if the EXHAUST PORT is not designed and located appropriately. Since the EXHAUST PORT location can affect REBREATHING, measuring only EXHAUST PORT pressure/flow characteristics might not be sufficient to ensure acceptable performance. This test measures CO_2 directly during simulated breathing that allows MASKS and other PATIENT interfaces to be compared with respect to REBREATHING in both NORMAL CONDITION and SINGLE FAULT CONDITION.

F.2 Apparatus

Figure F.1 illustrates the test setup for the determination of CO_2 REBREATHING testing.

Key

1 flow source
2 1,9 m ± 0,15 m BREATHING TUBE
3 MASK and, if applicable, connecting element
4 simulated PATIENT head
5 CO_2 monitor
6 dead space of 140 ml ± 5 ml
7 test lung simulator (driving ventilator + breathing simulator)
8 CO_2 constant flow source

NOTE 1 A lung chamber volume of approximately 10 l, with an active mixing fan, is recommended to ensure satisfactory mixing.

NOTE 2 Adapted from Reference.[3]

Figure F.1 — Test setup for CO_2 REBREATHING testing

F.3 Procedure

Carry out testing as follows.

a) *Assemble components as shown in Figure F.1.*

NOTE 1 *In the initial setup, the MASK is not attached to the simulated PATIENT head.*

NOTE 2 *The simulated PATIENT head has approximately 30 ml of internal volume between the gas sampling port and the nose/mouth to simulate a PATIENT airway.*

b) *Set breathing simulator parameters:*

1) *tidal volume = 0,5 l;*

2) *rate = 15 breaths/min;*

3) *I:E ratio = 1:2;*

4) *sinusoidal waveform.*

c) *Connect the CO_2 monitor to the gas sampling port via gas sampling line.*

d) *Connect the source of gas containing greater than 99 % CO_2 via a flow meter into the lung simulator. Confirm a constant flowrate.*

e) *Start the lung and breathing simulator and slowly increase gas flow until the end-expiratory peak CO_2 reading is approximately a volume fraction of 5 %. Allow sufficient time for simulation to equilibrate and reading to stabilize.*

NOTE A volume fraction of 5 % simulates normal metabolic CO_2 production.

f) *Record the end-expiratory CO_2 concentration.*

NOTE A time greater than three times the time constant (i.e. three times the ratio of the volume of the lung chamber and the simulated alveolar ventilation) is sufficient.

g) *Secure the test MASK to simulated PATIENT head. Confirm that the MASK is completely sealed to the face portion of the simulated PATIENT head, with no unintentional leaks.*

h) *Set the pressure source to generate the minimum RATED pressure of the MASK including any connecting element.*

i) *Allow sufficient time for the simulation to equilibrate and the CO_2 reading to stabilize. Then record the end-expiratory CO_2 concentration.*

j) *Calculate the relative CO_2 increase by computing the percentage difference between the final and initial end-expiratory CO_2 concentrations, i.e. 100 times [the value in i) minus the value in f)] divided by the value in f).*

k) *Set the pressure source to generate a pressure of approximately 5 hPa (5 cmH_2O).*

l) *Repeat steps e) to j).*

m) *Set the pressure source to generate a pressure of approximately 10 hPa (10 cmH_2O).*

n) *Repeat steps e) to j).*

o) *For MASKS that cover the mouth, simulate the following SINGLE FAULT CONDITIONS, one at a time:*

— *blockage of the BREATHING TUBE (simulated by occluding the PATIENT-CONNECTOR PORT);*

— *failure of the equipment to generate flow (simulated by connecting one end of the BREATHING TUBE to the PATIENT-CONNECTOR PORT with the other end open to atmosphere).*

p) *Repeat steps e) to j).*

Annex G
(normative)

Vibration and noise

G.1 Principle

The objective of the vibration and noise test is to measure the acoustic noise generated by the MASK and any ACCESSORY exclusive of the noise generated by the BREATHING TUBE or the SLEEP APNOEA BREATHING THERAPY EQUIPMENT.

G.2 Apparatus

The following items are utilized:

a) the MASK or ACCESSORY under test;

b) BREATHING TUBE and the SLEEP APNOEA BREATHING THERAPY EQUIPMENT recommended by the MANUFACTURER;

c) microphone of the sound level meter complying with the requirements of class 1 instruments specified in IEC 61672-1:2013;

d) sound level meter with frequency-weighting characteristic A and the time-weighting characteristic F as specified in ISO 3744:2010.

G.3 Procedure

Carry out testing as follows.

a) *Seal the PATIENT interface of the MASK or ACCESSORY and place the MASK and any ACCESSORY on the sound-reflecting plane.*

b) *Fit the BREATHING TUBES and equipment provided or recommended by the MANUFACTURER.*

c) *If a humidifier is provided with the equipment, include the humidifier in the test.*

d) *Acoustically insulate the BREATHING TUBES and equipment by a suitable means out of the testing area so that the noise caused by the BREATHING TUBE and the gas flow does not interfere with the sound measurement of the MASK and any ACCESSORY.*

NOTE *The insulation is intended to ensure that the noise emitted by the BREATHING TUBE or the equipment or the noise conducted by the airflow does not interfere with the sound measurement of the MASK or ACCESSORY.*

e) *Set the equipment to achieve a continuous pressure of 10 hPa (10 cmH_2O) at the PATIENT-CONNECTION PORT.*

f) *Using the microphone of the sound level meter complying with the requirements of class 1 instruments specified in IEC 61672-1:2013, measure the sound pressure levels in accordance with ISO 3744:2010, 8.2.1, at 10 positions in a hemisphere with a radius of 1 m to the geometric centre of the mask and any accessories in a free field on the reflecting plane as specified in ISO 3744:2010, 7.2.3 and 8.1.1. ISO 3744:2010, Annex F, shall not be utilized.*

g) *Confirm that the A-weighted background level of extraneous noise is at least 6 dB below that measured during the test.*

h) *Calculate the A-weighted sound pressure level averaged over the measurement surface according to ISO 3744:2010, 8.2.4.*

i) *Calculate the A-weighted sound power level according to ISO 3744:2010, 8.2.5.*

Annex H
(informative)

Guide to information to be supplied by the MANUFACTURER

H.1 Marking on the protective packaging of a MASK or ACCESSORY

The requirements for marking on the protective packaging of a MASK or ACCESSORY are found in 4.2. Additional requirements are found in the subclauses listed in Table H.1.

Table H.1 — Marking

Description of information	Subclause
If containing phthalates, containing phthalates	5.2

H.2 Accompanying document for mask or accessory

The requirements for information to be included in the ACCOMPANYING DOCUMENTS of a MASK or ACCESSORY are found in 4.3. Additional requirements are found in the subclauses listed in Table H.2.

Table H.2 — ACCOMPANYING DOCUMENT

Description of information	Subclause
PROCESSING or (re)PROCESSING instructions	5.4
If containing phthalates, information regarding the RESIDUAL RISKS and, if applicable, on appropriate precautionary measures	5.2
If provided, ANTI-ASPHYXIA VALVE open-to-atmosphere pressure	5.5
If provided, ANTI-ASPHYXIA VALVE closed-to-atmosphere pressure	5.5
Sound power level	6
Sound pressure level	6

Annex I
(informative)

Reference to the essential principles

This International Standard has been prepared to support the essential principles of safety and performance of MASKS and ACCESSORIES of SLEEP APNOEA BREATHING THERAPY EQUIPMENT as medical devices according to ISO/TR 16142:2006. This International Standard is intended to be acceptable for conformity assessment purposes.

Compliance with this International Standard provides one means of demonstrating conformance with the specific essential principles of ISO/TR 16142:2006. Other means are possible. Table I.1 maps the clauses and subclauses of this International Standard with the essential principles of ISO/TR 16142:2006.

Table I.1 — Correspondence between this International Standard and the essential principles

Essential principle of ISO/TR 16142:2006	Corresponding clause(s)/subclause(s) of this International Standard	Qualifying remarks/notes
A.1, A.2, A.3	All	
A.4	5	
A.5	—	Not addressed
A.6	—	Not addressed
A.7.1	5.2, 5.4	
A.7.2	5	
A.7.3	5.2, 5.4	
A.7.4	—	Not applicable
A.7.5	5	
A.7.6	5	
A.8.1	5.4, 5.6	
A.8.1.1	—	Not applicable
A.8.1.2	—	Not applicable
A.8.2	5.4	
A.8.3	5.4	
A.8.4	5.4	
A.8.5	5.4, 4.3 l)	
A.8.6	4.2 i), 4.3 d)	
A.9.1	5.3, 4.3 h), 4.3 j), 4.3 p), 4.3 q), 4.3 r)	
A.9.2	5.3, 5.5	
A.9.3	—	Not applicable
A.10.1	—	Not applicable
A.10.2	—	Not applicable
A.10.3	—	Not applicable
A.11.1.1	—	Not applicable
A.11.2.1	—	Not applicable
A.11.2.2	—	Not applicable
A.11.3.1	—	Not applicable

Table I.1 *(continued)*

Essential principle of ISO/TR 16142:2006	Corresponding clause(s)/subclause(s) of this International Standard	Qualifying remarks/notes
A.11.4.1	—	Not applicable
A.11.5.1	—	Not applicable
A.11.5.2	—	Not applicable
A.11.5.3	—	Not applicable
A.12.1	—	Not applicable
A.12.2	—	Not applicable
A.12.3	—	Not applicable
A.12.4	—	Not applicable
A.12.5	—	Not applicable
A.12.6	—	Not applicable
A.12.7.1	—	Not applicable
A.12.7.2	6	
A.12.7.3	6	
A.12.7.4	5.1	
A.12.7.5	—	Not applicable
A.12.8.1	5.5	
A.12.8.2	5.3, 5.5	
A.12.8.3	—	Not applicable
A.13.1	4	
A.14.1	—	Not addressed

Annex J
(informative)

Terminology — alphabetized index of defined terms

ACCESSORY	IEC 60601-1:2005+A1:2012, 3.3
ACCOMPANYING DOCUMENT	IEC 60601-1:2005+A1:2012, 3.4
ANTI-ASPHYXIA VALVE	3.1
BREATHING GAS PATHWAY	ISO 80601-2-70:2015, 201.3.204
BREATHING SYSTEM FILTER	ISO 23328-2:2002, 3.1
BREATHING TUBE	ISO 4135:2001, 4.1.2
CLEANING	ISO 17664:2004, 2.2
DISINFECTION	ISO 17664:2004, 2.3
EXHAUST FLOW	3.2
EXHAUST PORT	ISO 4135:2001, 4.2.1.6
EXPECTED USEFUL LIFE	3.3
GAS OUTPUT PORT	ISO 4135:2001, 3.2.8
HARM	ISO 14971:2007, 2.2
HEADGEAR	3.4
INTENDED USE	ISO 14971:2007, 2.5
MANUFACTURER	IEC 60601-1:2005+A.1:2012, 3.55
MASK	3.5
ME EQUIPMENT	IEC 60601-1:2005+A.1:2012, 3.63
MEDICAL DEVICE	ISO 14971:2007, 2.9
MODEL OR TYPE REFERENCE	IEC 60601-1:2005+A.1:2012, 3.66
MULTI-PATIENT REUSE	3.6
NORMAL CONDITION	IEC 60601-1:2005+A.1:2012, 3.70
NORMAL USE	IEC 60601-1:2005+A.1:2012, 3.71
OPERATOR	IEC 60601-1:2005+A.1:2012, 3.73
ORAL APPLIANCE	3.7
PATIENT	IEC 60601-1:2005+A.1:2012, 3.76
PATIENT-CONNECTION PORT	ISO 4135:2001, 4.2.1.2
PROCESS	ISO 14971:2007, 2.13
PROCESSING	ISO 17664:2004, 2.6
RATED	IEC 60601-1:2005+A.1:2012, 3.97
REBREATHING	ISO 4135:2001, 4.1.4
RESIDUAL RISK	ISO 14971:2007, 2.15
RESPONSIBLE ORGANIZATION	IEC 60601-1:2005+A.1:2012, 3.101
RISK	ISO 14971:2007, 2.13
RISK MANAGEMENT FILE	ISO 14971:2007, 2.23
RISK MANAGEMENT	ISO 14971:2007, 2.22

SINGLE FAULT CONDITION	3.8
SINGLE-PATIENT REUSE	3.9
SLEEP APNOEA BREATHING THERAPY EQUIPMENT	ISO 80601-2-70:2015, 201.3.212

Bibliography

[1] ISO/TR 16142:2006, *Medical devices — Guidance on the selection of standards in support of recognized essential principles of safety and performance of medical devices*

[2] ISO 17510-1:2007, *Sleep apnoea breathing therapy — Part 1: Sleep apnoea breathing therapy equipment*

[3] ISO 17510-2:2007, *Sleep apnoea breathing therapy — Part 2: Masks and application accessories*

[4] ISO 14971:2007, *Medical devices — Application of risk management to medical devices*

[5] ISO 18562-1[1)], *Biocompatibility evaluation of respiratory gas pathways in healthcare applications — Part 1: Evaluation and testing within a risk management process*

[6] AAMI TIR 12:1994, *Designing, Testing and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities, A Guide for Device Manufacturers*

[7] ASTM F1246-91:2005, *Standard Specification for Electrically Powered Home Care Ventilators, Part 1: Positive-Pressure Ventilators and Ventilator Circuits*

[8] FARRE. R., MONTSERRAT, J.M., BALLESTER, E. and NAVAJAS, D. Potential Rebreathing After Continuous Positive Airway Pressure Failure During Sleep. Chest. 2002, **121** pp. 186—200

[9] GUILHERME. P.P., SCHETTINO, S.C., HESS, D.R. and KACMAREK, R.M. Position of exhalation port and mask design affect CO2 rebreathing during non-invasive positive pressure ventilation. Crit. Care Med. 2003, **31** (8) pp. 2178–2182

1) To be published.